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# **China, People's Republic of**

## **Food and Agricultural Import Regulations and Standards**

### **Ministry of Health Admin Measures for GM Food Hygiene**

### **2002**

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#### **Report Highlights:**

**This is an UNOFFICIAL English translation of the People's Republic of China Administrative Measures for Genetically Modified Food Hygiene and should be used as a guide only. Exporters should carefully discuss regulations and their application with Chinese importers to ensure that their interpretation of the regulation is accurate.**

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Includes PSD changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Beijing [CH1], CH

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Beijing, People's Republic of China for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

### **Summary**

The following is Decree No. 28 from the PRC Ministry of Health (MOH). This is an UNOFFICIAL English translation of the "Administration Measures for Genetically Modified Food Hygiene." This measure was reviewed and approved on December 11, 2001 by the executive committee of the Ministry of Health. The document was published and will take effect on July 1, 2002.

However, as of now, the Ministry of Health has not issued the more detailed "Implementation Measures for Genetically Modified Food Hygiene." Once the "Implementation Measures" are published, manufacturers and processors using GM ingredients should know how to comply with the measures. The "GM food catalogue" mentioned in Article 15 is not available. In addition, the Ministry of Health has issued a public notice declaring that it will begin accepting evaluation applications after December 21, 2002.

These measures establish an application system for the use of GM food and food ingredients in food manufacturing or processing along with an evaluation system for GM food quality and safety. The measures require GM foods and foods made from GM materials to be labeled. Finally, the measures introduce a monitoring system for processors or manufacturers of foods using genetically engineered ingredients or raw materials .

## **Administrative Measures for Genetically Modified Food Hygiene**

### **Chapter I. General Provisions**

Article 1. Based on the Food Hygiene Law (CH1042) of the People's Republic of China (hereinafter referred to as "Food Hygiene Law") and Ag GMO Safety Administration Regulations (CH1056), these measures are established to strengthen the monitoring and administration of genetically modified (GM) food and protect consumers' rights of health and awareness.

Article 2. "GM food" mentioned in these measures refers to food and food additives that are made from animals, plants and microorganisms whose genome structures have been modified through genetic engineering technology. This includes:

- 1) genetically modified animals, plants, or microorganism products.
- 2) products directly processed from genetically modified animals, plants, or microorganisms.
- 3) food and food additives made from raw materials of genetically modified animals, plants, or microorganisms or their directly processed products.

Article 3. Being a new source of food, GM food shall be produced or imported after it has been reviewed and

approved by the Ministry of Health. GM food shall not be produced or imported without the review and approval of the Ministry of Health, nor shall it be used as food or food raw material.

Article 4. GM foods shall comply with relevant rules, regulations, or standards and shall not pose any acute, chronic, or potential health hazard to humans.

Article 5. The safety and nutritional quality of GM food shall not be lower than that of the corresponding original (or non-GM) food.

Article 6. The manufacturer of GM food shall meet the requirements of the state regulations with regard to food manufacturers.

The manufacturer of GM food shall ensure the safety and nutritional quality of the GM food being manufactured or processed.

The manufacturer of GM food shall keep a record on the purchase (or sale) of GM food, including purchasing (or sale) unit name, address, and quantity. The related records shall be kept for at least two years for the purpose of inspection.

## **Chapter II. Evaluation of Food Safety and Nutritional Quality**

Article 7. The Ministry of Health shall set up an evaluation system for GM food safety, and nutritional quality. MOH shall promulgate and publicize the procedures and related standards with regard to the evaluation of GM food safety and nutritional quality.

Article 8. The evaluation of GM food safety and nutritional quality will be conducted on a case by case basis in accordance with the principles of risk assessment and substantial equivalence.

Article 9. MOH will form a GM food expert committee composed of experts of food safety, nutrition, and genetic engineering to take charge of the evaluation of food safety and nutritional quality.

Article 10. As required for the evaluation of GM food safety and nutritional quality, MOH will accredit qualified testing agencies to undertake verification of evaluation of GM food safety and nutritional quality.

## **Chapter III. Application and Approval**

Article 11. The manufacturer or importer of GM food shall apply to MOH with the following materials:

- 1) application form
- 2) approval documents issued by relevant government departments
- 3) enterprise standards
- 4) safeguard measures for food safety
- 5) packaging design and labeling sample
- 6) technical documents that relate to the evaluation of GM food safety and nutritional quality
- 7) evaluation report of applicant on GM food safety and nutritional quality and verification report on GM food safety and nutritional quality produced by a MOH accredited testing agency.
- 8) other materials conducive to the evaluation of GM food safety and nutritional quality.

Article 12. Technical documents that relate to the evaluation of GM food safety and nutritional quality as stated in Item 6 of Article 11 include:

- 1) name of GM food (specie)

- 2) physical/chemical features, usage and special functions of GM food
- 3) possible processing method(s) of GM food, category of final product(s) and main ingredients (including nutritional and harmful ingredients)
- 4) objective of genetic modification and expected technical effects, and the anticipated impact on food product features
- 5) name, features and edibility history of gene provider; the source, features, functions and edibility history of carrier material; and insert positioning of gene and its features
- 6) name, features, functions, and content of the expressed product of the introduced gene
- 7) known or suspected allergic and toxic features of the expressed product, and evidence of food safety of the expressed product.
- 8) possible unexpected effects (including the evaluation of metabolism)

Article 13. In addition to the required materials listed in Article 11 and 12, the applicant for GM food imports shall also supply certification documents from the government of the exporting country (region) showing the product has been approved for production, operation, and use in the country (region).

Article 14. The Ministry of Health shall decide whether to approve the application within 6 months following receipt of a GM food application.

Article 15. MOH will list the approved GM foods in the GM food catalogue that are eligible for food production and operation.

#### **Chapter IV. Labeling**

Article 16. Food product (including raw material and its processed food) that contains GM organism and/or GM expressed product shall be labeled as "GM XX food" or "made from GM XX food".

GM food that derives from potential allergic food shall also be labeled "this product is modified from XX food gene, those who are allergic to XX food should take caution".

Article 17. GM food shall be labeled in the following manners:

- 1) products in package: indicated a marked position on the label
- 2) product in bulk: indicated on the label or separately arranged sign board.
- 3) product in transshipment: indicated on the bill of lading
- 4) imported product: indicated in the business contract and customs declaration form

Article 18. The labeling of GM food shall be authentic and objective, and must be free from the following content:

- 1) indication or implication of the ability to cure disease
- 2) falsification or fabrication of product function
- 3) other contents that MOH has banned for labeling

#### **Chapter V. Monitoring**

Article 19. MOH will re-evaluate the GM food that has been approved for production or importation if one of the following situations has been found:

- 1) Scientific knowledge on the GM food safety and nutritional quality has changed;
- 2) The GM food safety and nutritional quality is questionable;
- 3) Other reasons that require re-evaluation.

Article 20. MOH will arrange for regular or random monitoring inspections of GM food producers and operators.

Article 21. The MOH accredited testing agencies responsible for the evaluation of GM food safety and nutritional quality shall conduct the evaluation in accordance with the procedures and related standards stipulated by MOH.

In case a testing agency produces a false inspection report or fails to ensure inspection quality due to negligent management, MOH will order the action corrected, publish a criticism, and, in severe cases, have the accreditation revoked.

Article 22. The personnel engaged in GM food inspection, review, and monitoring shall be equipped with professional skills and occupational morality.

Article 23. The regular hygiene monitoring management for GM food production and operation shall be executed based on the Food Hygiene Law and related regulations.

#### **Chapter VI. Supplementary Provisions**

Article 24. Violators of these measures shall be penalized by the health executive department based on the related provisions of the Food Hygiene Law.

Article 25. MOH shall be responsible for interpretation of these measures.

Article 26. These measures shall take effect as of July 1, 2002.